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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,507	03/30/2004	John S. Lollar	13097/3	5299

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EXAMINER	
GIBBS, TERRA C	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/813,507	LOLLAR, JOHN S.	
	Examiner	Art Unit	
	Terra C. Gibbs	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-26 are pending in the instant application.

Claims 1-26 are subject to restriction as detailed below:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Election/Restrictions

Group I. Claims 1-4, drawn to an isolated polypeptide comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:15, classifiable in class 435, subclass 69.1.

Group II. Claims 1-4, drawn to an isolated polypeptide comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:17, classifiable in class 435, subclass 69.1.

Group III. Claims 1-4, drawn to an isolated polypeptide comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:19, classifiable in class 435, subclass 69.1.

Group IV. Claims 5-18, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:14, vectors, and cells comprising said nucleic acid molecule, and a method of making a polypeptide following expression of said isolated nucleic acid molecule, classifiable in class 536, subclass 23.1.

Group V. Claims 5-18, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:16, vectors, and cells comprising said nucleic acid molecule, and a method of making a polypeptide following expression of said isolated nucleic acid molecule, classifiable in class 536, subclass 23.1.

Group VI. Claims 5-18, drawn to an isolated nucleic acid molecule comprising a nucleotide sequence having at least 85% sequence identity to SEQ ID NO:18, vectors, and cells comprising said nucleic acid molecule, and a method of making a polypeptide following expression of said isolated nucleic acid molecule, classifiable in class 536, subclass 23.1.

Group VII. Claims 19-22, 25, and 26, drawn to a method of treating a factor VIII deficiency in a subject, comprising administering a nucleic acid molecule having at least 85% sequence identity to SEQ ID NO:14, classifiable in class 514, subclass 44.

Group VIII. Claims 19-22, 25, and 26, drawn to a method of treating a factor VIII deficiency in a subject, comprising administering a nucleic acid molecule having at least 85% sequence identity to SEQ ID NO:16, classifiable in class 514, subclass 44.

Group IX. Claims 19-22, 25, and 26, drawn to a method of treating a factor VIII deficiency in a subject, comprising administering a nucleic acid

molecule having at least 85% sequence identity to SEQ ID NO:18, classifiable in class 514, subclass 44.

Group X. Claims 23 and 24, drawn to a method of treating a factor VIII deficiency in a subject, comprising administering a polypeptide comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:15, classifiable in class 514, subclass 2.

Group XI. Claims 23 and 24, drawn to a method of treating a factor VIII deficiency in a subject, comprising administering a polypeptide comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:17, classifiable in class 514, subclass 2.

Group XII. Claims 23 and 24, drawn to a method of treating a factor VIII deficiency in a subject, comprising administering a polypeptide comprising an amino acid sequence having at least 85% sequence identity to SEQ ID NO:19, classifiable in class 514, subclass 2.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Groups IV-VI and X-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleic acid molecules comprising SEQ ID NOs:14, 16, and 18 of Groups IV-VI, respectively, can be as a hybridization probes in methods of identifying factor VIII mRNA expression, which is an entirely different process than methods of treating a factor VIII deficiency in a subject as recited in Groups X-XII. Therefore, Groups IV-VI are distinct from Groups X-XII, since the composition of Groups IV-VI can be used in materially distinct methods than those recited in Groups X-XII.

Searching the inventions of Groups I-III together, in one application, would impose a serious search burden. The inventions of Groups I-III are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups I-III are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches

of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the isolated polypeptide comprising SEQ ID NO:15 of Group I would not necessarily encompass all of the art relevant to the isolated polypeptide comprising SEQ ID NO:17 of Group II or the isolated polypeptide comprising SEQ ID NO:19 of Group III. Similarly, a search of the isolated polypeptide comprising SEQ ID NO:17 of Group II would not necessarily encompass all of the art relevant to the isolated polypeptide comprising SEQ ID NO:19 of Group III. Since a search of Group I would not encompass all the art relevant to Groups II and III, and a search of Group II would not encompass all of the art relevant to Group III, the inventions are not coextensive. Since the search for Groups I-III are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Therefore, they are patentably distinct from each other.

Searching the inventions of Groups IV-VI together, in one application, would impose a serious search burden. The inventions of Groups IV-VI are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups IV-VI are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the isolated nucleic acid comprising SEQ ID NO:14 of Group IV would not necessarily encompass all of the art relevant to the isolated

nucleic acid comprising SEQ ID NO:16 of Group V or the isolated nucleic acid comprising SEQ ID NO:18 of Group VI. Similarly, a search of the isolated nucleic acid comprising SEQ ID NO:16 of Group V would not necessarily encompass all of the art relevant to the isolated nucleic acid comprising SEQ ID NO:18 of Group VII. Since a search of Group IV would not encompass all the art relevant to Groups V and VI, and a search of Group V would not encompass all of the art relevant to Group VI, the inventions are not coextensive. Since the search for Groups IV-VI are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. Therefore, they are patentably distinct from each other.

Searching the inventions of Groups VII-IX together would impose a serious search burden. Although the methods of Groups VII-XII are related because they recite a method of treating a factor VIII deficiency in a subject, comprising administering a nucleic acid molecule, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method of using the isolated nucleic acid comprising SEQ ID NO:14 of Group VII would not necessarily encompass all of the art relevant to the method of using the isolated nucleic acid comprising SEQ ID NO:16 of Group VIII or the method of using the isolated nucleic

acid comprising SEQ ID NO:18 of Group IX. Similarly, a search of the method of using the isolated nucleic acid comprising SEQ ID NO:16 of Group VIII would not necessarily encompass all of the art relevant to the method of using the isolated nucleic acid comprising SEQ ID NO:18 of Group IX. Since a search of Group VII would not encompass all the art relevant to Groups VIII and IX, and a search of Group VIII would not encompass all of the art relevant to Group IX, the inventions are not coextensive. Since the search for Groups VII-IX are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. They are materially distinct methods which differ in reagents used and criteria for success, and thus they are patentably distinct from each other.

Searching the inventions of Groups X-XII together would impose a serious search burden. Although the methods of Groups X-XII are related because they recite a method of treating a factor VIII deficiency in a subject, comprising administering a nucleic acid molecule, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method of using the isolated polypeptide comprising SEQ ID NO:15 of Group X would not necessarily encompass all of the art relevant to the method of using the isolated

polypeptide comprising SEQ ID NO:17 of Group XI or the method of using the isolated polypeptide comprising SEQ ID NO:19 of Group XII. Similarly, a search of the method of using the isolated polypeptide comprising SEQ ID NO:17 of Group XI would not necessarily encompass all of the art relevant to the method of using the isolated polypeptide comprising SEQ ID NO:19 of Group XII. Since a search of Group X would not encompass all the art relevant to Groups XI and XII, and a search of Group XI would not encompass all of the art relevant to Group XII, the inventions are not coextensive. Since the search for Groups X-XII are not entirely coextensive, it would be burdensome to search the inventions of these Groups together in one application. They are materially distinct methods which differ in reagents used and criteria for success, and thus they are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg
August 7, 2006